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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/524,666	03/13/2000	John G. Aceti	SMI-13459pA	6745

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DABNEY, PHYLESHA LARVINIA

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

2643

DATE MAILED: 03/29/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/524,666	ACETI ET AL.
	Examiner	Art Unit
	Phylesha L Dabney	2643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 13 March 2000.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-57 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-50, 55-57 is/are rejected.

7) Claim(s) 51-54 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

This action is in response to the application received on 13 March 2000 in which claims 1-57 are pending.

Claim Objections

1. Claims 1-2, 4, 6, and 20 are objected to because of the following informalities: in the first line, the word "air" should be "aid". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In figures 14-15, it is not clearly shown that the isolator 64 is within something.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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3. Claims 1, 8, and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by **Voroba et al** (U.S. Patent No. 4,870,688); **Schlaegel et al** (U.S. Patent No. 5753870); **Weeks** (U.S. Patent No. 5748743); or **Killion** (U.S. Patent No. 4,170,720).

Regarding claims 1 and 55, Voroba, Schlaegel, Weeks, or Killion discloses a hearing aid comprising a base unit (99-100, Voroba; 36, Schlaegel; 1, Weeks; 10, Killion), and an earmold (30; 10; 10; fig. 1) comprising a compliant material and a retention mechanism (20,40,50,52; 18, 20, 38; col. 3 lines 34-35; fig. 1, threads between sound tube and BTE hearing aid).

Regarding claim 8, Voroba, Schlaegel, Weeks, and/or Killion discloses the earmold forms an earmold tip (see figures).

4. Claims 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by **Voroba et al** (U.S. Patent No. 4,870,688); or **Weeks** (U.S. Patent No. 5748743).

Regarding claim 9, Voroba and Weeks discloses the earmold forms an earmold sleeve.

Regarding claim 10, Voroba and Weeks discloses the earmold forms an earmold tip and sleeve.

5. Claims 56-57 are rejected under 35 U.S.C. 102(b) as being anticipated by **Voroba et al** (U.S. Patent No. 4,870,688); **Weeks** (U.S. Patent No. 5748743); or **Killion** (U.S. Patent No. 4,170,720).

Regarding claim 56, Voroba, Weeks, and/or Killion discloses the covering comprising a receiver (70; near 17; fig. 1, receiver).

Regarding claim 57, refer to claims 55 and 56.

6. Claims 11-19, 23, 24, and 44-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Voroba et al (U.S. Patent No. 4,870,688).

Regarding claims 11, 13, 15, and 17-19, Voroba discloses a modular hearing aid comprising: a base unit (99, 100), an earmold (30) comprising a compliant material and a retention mechanism (20,40,50,52), and a module (70; 90,101) comprising a shell (72) and electronics (70; 60, 90).

Regarding claims 12 and 14, Voroba discloses the earmold comprises a battery (80) removable attached to the earmold.

Regarding claim 16, Voroba discloses the module (90, 101) comprises a microphone (90).

Regarding claim 23, Voroba discloses replacing a base unit of a hearing aid comprising the steps: providing a modular hearing aid (10) having a base unit (200) an earmold (30) and a module component (70); releasing a securing mechanism (50, 52, 244, 246, 248); removing the base unit (200); discarding the base unit (col. 5, lines 23-52); placing a second base unit (col. 5 lines 23-27) onto the earmold; and attaching the securing mechanism (50, 52, 110, 112).

Regarding claim 24, Voroba discloses replacing a base unit of a hearing aid comprising the steps: providing a modular hearing aid (10) having a base unit (200) an earmold (30) and a module component (70); releasing a securing mechanism (50, 52, 110, 112); removing a component (70, 80, 90, or 110,); discarding the component (col. 3, lines 33-45 and col. 4, lines 41-44); replacing the component (70, 80, 90, or 110); and attaching the securing mechanism (50, 52, 110, 112).

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Regarding claims 44, and 46-47, Voroba discloses a hearing aid comprising a base unit (70, 90, 99, 100, 110, 200) and a potting material (72, 92).

Regarding claim 45, Voroba discloses the hearing aid is disposable (col. 7, lines 25-50).

7. Claims 48-50 are rejected under 35 U.S.C. 102(b) as being anticipated by **Voroba** (WO 93/25053) or **Birkholz et al** (U.S. Patent No. 4,840,249).

Regarding claim 48, Voroba or Birkholz discloses a hearing aid comprising a hearing aid portion (Voroba, 25; Birkholz, 1); flexible core (Voroba, 30; Birkholz, 11); and a compliant tip portion (Voroba, 32-33; Birkholz, 25).

Regarding claim 49, Voroba discloses the tip material comprising layers of fingers (33).

Regarding claim 50, Voroba discloses the layer of fingers comprising an elastomer material (page 9 line 33 through page 10 line 3; specifically silicone rubber is a known elastomeric material).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Diethelm** (U.S. Patent No. 3,852,540), in view of **Voroba et al** (U.S. Patent No. 4,870,688).

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Regarding claims 1-2, and 8-10, Diethelm teaches a base unit (2), an earmold (1, 3) removable attached to the base unit, a retention mechanism (col. 3 lines 13-34), and the earmold comprising a battery (7, 8). Diethelm does not teach the type of material used for the earmold; however, it is known in the art, as evidenced by Voroba (30), to use soft, malleable, compliant material for the earmold to facilitate comfort to the user. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the shell of Diethelm from a soft, malleable, compliant material to facilitate comfort to the user.

Regarding claim 3, Diethelm teaches a shell integrated with the earmold (1, 3) and housing the battery (8) and a receiver (5).

Regarding claim 4, Diethelm teaches a base unit (2), an earmold (1, 3) removable attached to the base unit, a retention mechanism (col. 3 lines 13-34), and the earmold comprising a battery (7, 8) and receiver (5). Diethelm does not teach the type of material used for the earmold; however, it is known in the art, as evidenced by Voroba (30), to use soft, malleable, compliant material for the earmold to facilitate comfort to the user. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the shell of ~~Diethelm~~ from a soft, malleable, compliant material to facilitate comfort to the user.

Regarding claim 5, Diethelm teaches a shell integrated with the earmold (1, 3) and housing the battery (8) and a receiver (5).

Regarding claim 6, Diethelm teaches a base unit (2), an earmold (1, 3) removable attached to the base unit, a retention mechanism (col. 3 lines 13-34), and the earmold comprising a receiver (5) and a shell (1, 1a). Diethelm does not teach the type of material used for the earmold; however, it is known in the art, as evidenced by Voroba (30), to use soft, malleable,

compliant material for the earmold to facilitate comfort to the user. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the shell of Diethelm from a soft, malleable, compliant material to facilitate comfort to the user.

Regarding claim 7, Diethelm teaches the receiver (5) is integrated with the earmold.

9. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Diethelm** (U.S. Patent No. 3,852,540), in view of **Voroba** (U.S. Patent No. 4,870,688), and further in view of **Knudsen** (U.S. Patent No. 2,246,737).

Regarding claims 20 and 21, Diethelm teaches a base unit (2), an earmold (1, 3) comprising a battery (7, 8) and receiver (5), and a retention mechanism (col. 3 lines 13-34). Diethelm does not teach the type of material used for the earmold; however, it is known in the art, as evidenced by Voroba (30), to use soft, malleable, compliant material for the earmold to facilitate comfort to the user. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the shell of Diethelm from a soft, malleable, compliant material to facilitate comfort to the user. Furthermore, the combination of Diethelm and Voroba does not teach the earmold having a flexible, mushroom shaped earmold tip. However, it is known in the art, as evidence by Knudsen (figs. 1-5), for an earmold tip to have horizontal flanges (Knudsen; 12) for tightly sealing the auditory canal to the outside, providing comfort to the user, and for simulating a mushroom shaped tip. Therefore, it would have been obvious to one of ordinary skill in the art to include the flange(s) onto the earmold (Diethelm; 1,

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3) of the combination of Diethelm and Voroba for tightly sealing the auditory canal to the outside and providing comfort to the user.

10. Claims ~~22, 25,~~ and 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Voroba (U.S. Patent No. 4,870,688) or Diethelm (U.S. Patent No. 3,852,540).

Regarding claims 25 and 31, Voroba or Diethelm teaches an earmold tip (Voroba, 30; Diethelm, 1, 3) comprising a vibration isolator portion (Voroba, 72; Diethelm, 1) adapted for attachment within a hearing aid, having a receiver (Voroba, 70; Diethelm, 5). Since neither Voroba nor Diethelm excludes the receiver from having a diaphragm and the Examiner takes official notice that it is well known in the art for a receiver to have vibratory elements, i.e. diaphragms, for transmitting audible sound to the user. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a diaphragm within the receiver of Voroba or Diethelm to transmit audible sound.

Regarding claim 32, Voroba or Diethelm teaches the hearing aid includes a base unit (Voroba, 99-100; Diethelm, 2) having a microphone Voroba, 90; Diethelm, 15).

Regarding claims 33 and 34, refer to claims 25 and 32.

Regarding claim 35, neither Voroba nor Diethelm teach using adhesive to secure the receiver to the earmold. However, the examiner takes official notice that it is extremely well known in the art to use adhesive for securely fixing the receiver to the earmold for the purpose of limiting distorted audible sound. Therefore, it would have been obvious to one of ordinary skill in the art that to securely attach the receiver to the earmold to prevent distorted audible sound.

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11. Claims 26-30, and 36-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Diethelm (U.S. Patent No. 3,852,540), in view of Knudsen (U.S. Patent No. 2,246,737).

Regarding claims 26, 27, and 40, Diethelm does not teach the earmold having a flexible, mushroom shaped earmold tip. However, it is known in the art, as evidence by Knudsen (figs. 1-5), for an earmold tip to have horizontal flanges (Knudsen; 12) for tightly sealing the auditory canal to the outside, providing comfort to the user, and for simulating a mushroom shaped tip. Therefore, it would have been obvious to one of ordinary skill in the art to include the flange(s) onto the earmold tip (Diethelm; 1, 3) for tightly sealing the auditory canal to the outside and providing comfort to the user.

Regarding claims 28, 30, and 38, Diethelm teaches the earmold tip comprising a sound bore (6, 6a, 22, 23).

Regarding claim 29, Diethelm does not teach a spring surrounding the sound bore. However, the examiner takes official notice that it is known in the art to insert springs into earmold tips to increase stiffness and control navigation of the tip along the ear canal. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a spring in the invention of Diethelm and Knudsen to increase stiffness and control navigation.

Regarding claims 36, 39, 41, refer to claims 25, 26, and 28.

Regarding claim 37, refer to claim 29.

Regarding claims 42 and 43, claims 25, 27, 34, 35, 36, 40, 41 cover the limitations of these claims.

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12. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Voroba et al** (U.S. Patent No. 4,870,688); **Schlaegel et al** (U.S. Patent No. 5753870); **Weeks** (U.S. Patent No. 5748743); or **Killion** (U.S. Patent No. 4,170,720).

Regarding claim 22, the references above teach all of the limitations (see claim 1 rejection) except placing a second earmold onto the base unit. For this limitation, the examiner takes official notice that it is known in the art to remove an earmold for cleaning and it is known for earmolds to tear and become brittle and need replacement after prolonged use. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to remove a defective earmold and replace it with a new earmold to satisfy the customer and prevent pieces of the earmold from being left in the ear canal.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phylesha L Dabney whose telephone number is 703-306-5415. The examiner can normally be reached on Mondays, Tuesdays, Wednesdays, Fridays 8:30-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Curtis Kuntz can be reached on 703-305-4708. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9314 for regular communications and 703-872-9314 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-4700.

Any response to this action should be mailed to:

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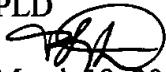
Or faxed to:

(703) 872-9314, for formal communications intended for entry and for informal or draft communications, please label "Proposed" or "Draft" when submitting an informal amendment.

(703) 306-0377, for customer service questions.

Hand-delivered responses should be brought to Crystal Park II, 2121 Crystal Drive, Arlington, VA., Sixth Floor (Receptionist).

PLD



March 18, 2002



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